K080092

510(k) Summary

JUL 2 8 2008

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

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Date Prepared: June 17, 2008

Device Name

Proprietary name: (1) Elecsys Anti-TSHR Immunoassay
(2) Elecsys PreciControl ThyroAB

Common name: (1) Anti-TSHR Assay
(2) PreciControl ThyroAB

Classification name: (1) System, Test, Thyroid Autoantibody
(2) Single (specified) analyte controls (Assayed and Unassayed)

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510(k) Summary, Continued

Device Description

(1) The Elecsys Anti-TSHR immunoassay is a three step competition principle immunoassay with streptavidin-coated microparticles and electrochemiluminescence detection. Results are determined using a calibration curve that is generated specifically on each instrument by a 2 point calibration and a master curve provided with the reagent bar code.
(2) The Elecsys PreciControl ThyroAB is a lyophilized product consisting of human serum with added Anti-TSHR antibody (human) in two concentration ranges. During manufacture, the antibody is spiked into the matrix at the desired concentration levels.
Note: The reagent and quality control material are packaged separately.

Intended use / Indications for Use

(1) Elecsys Anti-TSHR immunoassay: Immunoassay for the in vitro quantitative determination of autoantibodies to TSH receptor in human serum using a human thyroid stimulating monoclonal antibody. The anti-TSH receptor determination is used in the assessment of patients with suspect Graves' disease (autoimmune hyperthyroidism).
The **e**lectro**c**hemi**l**uminescence **i**mmuno**a**ssay "ECLIA" is intended for use on Elecsys and **cobas e** immunoassay analyzers.

(2) Elecsys PreciControl ThyroAB is used for quality control of the Elecsys Anti-TSHR immunoassay on the Elecsys and **cobas e** immunoassay analyzers.

Substantial equivalence

The Elecsys Anti-TSHR Test System is substantially equivalent to the following cleared device:

(1) Elecsys Anti-TSHR Immunoassay is equivalent to the BRAHMS LUMItest TRAK human Assay (K033454). Both products are intended for use in the quantitative determination of autoantibodies to TSH receptor in human serum.

(2) Elecsys PreciControl ThyroAB is equivalent to the controls contained in the BRAHMS LUMItest TRAK human Assay Kit (K033454).

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510(k) Summary, Continued

Substantial equivalence - comparison

The following table compares the Elecsys Anti-TSHR Immunoassay with the predicate device.

Immunoassay Comparison		
Feature	**Elecsys Anti-TSHR Assay**	**Predicate Device BRAHMS LUMItest TRAK human Assay (K033454)**
Intended Use	Immunoassay for the in vitro quantitative determination of autoantibodies to TSH receptor in human serum using a human thyroid stimulating monoclonal antibody. The anti-TSH receptor determination is used in the assessment of patients with suspect Graves' disease (autoimmune hyperthyroidism). The **electrochemiluminescence immunoassay** "ECLIA" is intended for use on Elecsys and **cobas e** immunoassay analyzers.	Luminescence receptor assay (LRA) for the quantitative determination of antibodies to the human thyrotropin (TSH) receptor.
Indication for Use	See intended use.	The measurement of TSH receptor autoantibodies is used in the assessment of patients with suspect Graves' disease (autoimmune hyperthyroidism).
Assay Protocol	Competition principle	same
Detection Protocol	**electrochemiluminescence immunoassay** (ECLIA)	Luminescence receptor assay (LRA)
Traceability/ Standardization	Standardized against NIBSC 1st IS 90/672 Standard	WHO 1st International reference material, 90/672 for TSAb
Calibration Interval	• Daily • As required: e.g. quality control findings outside the specified limits	N/A
Sample Type	Human serum	same

510(k) Summary, Continued

Substantial equivalence - comparison

The following table compares the Elecsys Anti-TSHR Immunoassay with the predicate device.

Immunoassay Comparison, continued		
Feature	**Elecsys Anti-TSHR Assay**	**Predicate Device BRAHMS LUMItest TRAK human Assay (K033454)**
Reagent Stability	• Unopened up to the stated expiration date stored at 2 – 8°C • On the analyzer: 72 hours if continuously stored onboard; or 2 weeks including up to 56 hours in total onboard if stored alternately in the refrigerator and on the analyzer	N/A
Calibrator	Anti-TSHR calibrators 1 and 2 supplied with kit	TRAK standards supplied with kit
Controls	Elecsys PreciControl ThyroAB	TRAC controls I and II supplied with kit
Pretreatment	Pretreatment 1: buffer solution Pretreatment 2: empty bottle for pretreatment reagent (PTR) reconstituted with pretreatment buffer (PTB) PTR: pretreatment reagent PTB: pretreatment buffer	Buffer for incubation of samples Buffer for reconstitution of tracer Tracer: luminescence-labeled b-TSH
Expected Values	Positive: > 1.75 IU/L	Negative: < 1 IU/L Equivocal: 1 – 2 IU/L Positive: > 2 IU/L
Instrument	Elecsys 2010, MODULAR ANALYTICS E170, **cobas e** 411, **cobas e** 601	Luminometer
Measuring Range	0.8 – 40 IU/L (defined by the limit of detection and the maximum of the master curve)	0.9 – 40 IU/L

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510(k) Summary, Continued

Substantial equivalence - comparison

The following table compares the performance of Elecsys Anti-TSHR Immunoassay with the predicate device.

Immunoassay Performance Comparison		
Feature	**Elecsys Anti-TSHR Assay**	**Predicate Device BRAHMS LUMItest TRAK human Assay (K033454)**
Precision	**Elecsys 2010 and cobas e 411:** **Within-run** 5.9% CV @ 1.73 IU/L 4.4% CV @ 2.57 IU/L 2.7% CV @ 6.57 IU/L 1.3% CV @ 25.5 IU/L 3.0% CV @ 3.60 IU/L 1.7% CV @ 15.0 IU/L **Total** 9.7% CV @ 1.73 IU/L 6.7% CV @ 2.57 IU/L 3.9% CV @ 6.57 IU/L 1.8% CV @ 25.5 IU/L 5.1% CV @ 3.60 IU/L 2.4% CV @ 15.0 IU/L **E170 and cobas e 601:** **Within-run** 7.6% CV @ 1.71 IU/L 5.1% CV @ 2.16 IU/L 1.9% CV @ 5.92 IU/L 0.9% CV @ 24.6 IU/L 3.1% CV @ 3.16 IU/L 1.4% CV @ 14.6 IU/L **Total** 11.4% CV @ 1.71 IU/L 8.7% CV @ 2.16 IU/L 3.8% CV @ 5.92 IU/L 1.9% CV @ 24.6 IU/L 5.5% CV @ 3.16 IU/L 2.4% CV @ 14.6 IU/L	**Interassay Precision:** Sample means 0.6 IU/L – 20.3 IU/L = %CV 4.1 – 35.1% **Intra-assay Precision:** Sample means 0.9 IU/L – 101.7 IU/L = % CV 2.3 – 24.2%

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510(k) Summary, Continued

Substantial equivalence - comparison

The following table compares the performance of Elecsys Anti-TSHR Immunoassay with the predicate device.

Immunoassay Performance Comparison, continued		
Feature	**Elecsys Anti-TSHR Assay**	**Predicate Device BRAHMS LUMItest TRAK human Assay (K033454)**
LoQ	0.9 IU/L	0.9 IU/L
Limit of Blank (LoB)	≤0.5 IU/L	0.4 IU/L
Limit of Detection LoD (Analytical Sensitivity)	≤0.8 IU/L	NA
Analytical Specificity	No interference with: • Anti-TG if less than 4000 IU/mL • Anti-TPO if less than 600 IU/mL • Human TSH if less than 1000 mIU/L • Human LH if less than 10,000 mIU/mL • Human FSH if less than 10,000 mIU/mL • hCG if less than 50,000 mIU/mL	No interference with : • Anti-TG if less than 2000 U/mL • Anti-TPO if less than 3000 U/mL • Human TSH if less than 1000 mU/L • Human LH if less than 9000 U/L • Human FSH if less than 15,000 U/L

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510(k) Summary, Continued

Substantial equivalence - comparison

The following table compares the performance of Elecsys Anti-TSHR Immunoassay with the predicate device.

Immunoassay Performance Comparison, continued		
Feature	**Elecsys Anti-TSHR Assay**	**Predicate Device BRAHMS LUMItest TRAK human Assay (K033454)**
Limitations	The assay is unaffected by: • Bilirubin: < 25 mg/dL • Hemoglobin: < 0.4 g/dL • Intralipid: < 1500 mg/dL • Biotin: < 10 ng/mL • Elevated results are obtained when using samples with biotin concentrations > 10 ng/mL • In patients receiving therapy with high biotin doses (i.e. >5 mg/day), no sample should be taken until at least 8 hours after the last biotin administration. • No interference was observed from rheumatoid factors up to a concentration of 600 IU/mL	• Hemoglobin: Concentrations: Not given Recovery: 100 – 125% • Bilirubin: Concentrations: 0.625, 1.25, 2.5, 5, 10, 20 mg/dL Recovery: 91 – 100% • Lipids: Concentration: dilutions prepared off of 634 mg/dL lipemic serum Recovery: 76 – 100%

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Substantial equivalence – comparison

The following table compares the performance of Elecsys Anti-TSHR Immunoassay with the predicate device.

Immunoassay Performance Comparison, continued		
Feature	**Elecsys Anti-TSHR Assay**	**Predicate Device BRAHMS LUMItest TRAK human Assay (K033454)**
Limitations, continued	• In vitro tests were performed on 20 commonly used pharmaceuticals. No interference with the assay was found except for heparin. In samples containing heparin elevated results are obtained. • The risk of interference from potential immunological interactions between test components and rare sera has been minimized by the inclusion of suitable additives. • In rare cases, interference due to extremely high titers of antibodies to streptavidin and ruthenium can occur. • For diagnostic purposes, the results should always be assessed in conjunction with the patients medical history, clinical examination and other findings	

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Substantial equivalence – comparison

The following table compares the performance of Elecsys Anti-TSHR Immunoassay with the predicate device.

<table>
<tr><th colspan="3">Immunoassay Performance Comparison, continued</th></tr>
<tr><th>Feature</th><th>Elecsys Anti-TSHR Assay</th><th>Predicate Device
BRAHMS LUMItest TRAK human Assay (K033454)</th></tr>
<tr><td>Method Comparison</td><td>A comparison of the Elecsys Anti-TSHR assay (y) with BRAHMS LUMItest TRAK human (x) using clinical samples gave the following correlations:
Number of samples measured: 212
Sample concentrations were between 1.1 IU/L and 40.0 IU/L

Passing/Bablok: 95% CI:
y = 1.183x – 0.316 Slope = 1.11 – 1.27
Intercept = -0.633 to -0.079
Concordance:
<table>
<tr><td rowspan="4">Elecsys Anti-TSHR</td><td colspan="4">Commercial anti-TSHR</td></tr>
<tr><td></td><td><1.0 IU/L</td><td>1.0 – 2.0[a] IU/L</td><td>>2.0 IU/L</td></tr>
<tr><td>>1.75 IU/L</td><td>7</td><td>11</td><td>199</td></tr>
<tr><td>≤1.75 IU/L</td><td>102</td><td>31</td><td>0</td></tr>
<tr><td>total</td><td>109</td><td>42</td><td>199</td></tr>
</table>
a. 42 results were excluded from the calculations after giving indeterminate results on the comparative method. A more differentiated analysis of the samples which gave indeterminate results in the comparative method shows that: 2 of the 11 samples positive with Elecsys Anti-TSHR have values from 1.75 – 2 IU/L, 9 of the 11 samples positive with Elecsys Anti-TSHR have values above 2 IU/L, 11 of the 31 samples negative with Elecsys Anti-TSHR have values below 1 IU/L and 20 of the 31 samples negative with Elecsys Anti-TSHR have values from 1 – 1.75 IU/L.
<table>
<tr><td>Agreement Classification</td><td></td><td>% Agreement (%)[b]</td><td>95% CI (%)</td></tr>
<tr><td>Neg. Agreement</td><td>102/ 109</td><td>93.6%</td><td>87.2 to 97.4</td></tr>
<tr><td>Pos. Agreement</td><td>199/ 199</td><td>100%</td><td>98.2 to 100</td></tr>
</table>
b. % positive of Elecsys Anti-TSHR among indeterminate results of comparative method equals 26.2% (11/42). % negative of Elecsys Anti-TSHR among indeterminate results of comparative method equals 73.8% (31/42).</td><td>A correlation study was performed between the predicate KRONUS TRAb assay and the LUMItest TRAK assay. Fifty-two (52) serum samples obtained from either confirmed Graves' disease patients or patients with non-Graves' thyroid disease were tested in parallel. Overall agreement between the two assays was 75.0%.</td></tr>
</table>

510(k) Summary, Continued

Substantial equivalence - comparison

The following table compares the calibrators supplied with the Elecsys Anti-TSHR immunoassay kit with the calibrators supplied with the predicate device.

Calibrator Comparison		
Feature	**Elecsys Anti-TSHR Assay**	**Predicate Device BRAHMS LUMItest TRAK human Assay (K033454)**
Levels	2	6
Format	Lyophilized	N/A
Matrix	human serum	same
Analyte Concentration (Anti-TSHR antibody; human)	Calibrator 1: 1.0 IU/L Calibrator 2: 25 IU/L	Calibrator 1: 0 IU/L Calibrator 2: 1 IU/L Calibrator 3: 2 IU/L Calibrator 4: 4 IU/L Calibrator 5: 16 IU/L Calibrator 6: 40 IU/L
Stability	Unopened: • Store at 2 – 8°C until expiration date. Reconstituted: • On the analyzers at 20 – 25°C: up to 3 hours • At -20°C: up to 3 months (freeze only once. • After thawing: use only once.	N/A

510(k) Summary, Continued

Substantial equivalence - comparison

The following table compares the calibrators supplied with the Elecsys Anti-TSHR immunoassay kit with the calibrators supplied with the predicate device.

Calibrator Comparison, continued		
Feature	**Elecsys Anti-TSHR Assay**	**Predicate Device BRAHMS LUMItest TRAK human Assay (K033454)**
Handling	Dissolve contents of one bottle by adding exactly 2.0 mL of distilled water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding the formation of foam. Transfer aliquots of freshly reconstituted controls into empty labeled snap-cap bottles. Attach the supplied labels to the additional bottles. Store the aliquots immediately at -20°C. Perform only one calibration procedure per aliquot.	N/A

510(k) Summary, Continued

Substantial equivalence - comparison

The following table compares the Elecsys PreciControl ThyroAB with the predicate device.

Control Comparison		
Characteristic	**Elecsys PreciControl ThyroAB**	**Predicate Device BRAHMS LUMItest TRAK human Assay (K033454)**
Intended Use	Used for quality control of the Elecsys Anti-TSHR immunoassay on the Elecsys and **cobas e** immunoassay analyzers.	N/A
Levels	Two	same
Format	Lyophilized	N/A
Matrix	Human serum	same
Stability	Unopened: • Store at 2 – 8°C until expiration date. Reconstituted: • On the analyzers at 20 – 25°C: up to 3 hours • At -20°C: up to 3 months (freeze only once. • After thawing: use only once.	N/A
Analyte Concentration PC 1	4 IU/L Anti-TSHR antibody (human)	Negative, indeterminate (actual concentration not given)
Analyte Concentration PC 2	16 IU/L Anti-TSHR antibody (human)	Positive (actual concentration not given)

510(k) Summary, Continued

Substantial equivalence - comparison

The following table compares the Elecsys PreciControl ThyroAB with the predicate device.

Control Comparison, continued		
Characteristic	**Elecsys PreciControl ThyroAB**	**Predicate Device BRAHMS LUMItest TRAK human Assay (K033454)**
Handling	Dissolve contents of one bottle by adding exactly 2.0 mL of distilled water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding the formation of foam. Transfer aliquots of freshly reconstituted controls into empty labeled snap-cap bottles. Attach the supplied labels to the additional bottles. Store the aliquots immediately at -20°C. Perform only one control procedure per aliquot.	N/A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Roche Diagnostics Corp.
c/o Ms. Stephanie Greeman
Regulatory Affairs Consultant
9115 Hague Road
Box 50416
Indianapolis, IN 46250-0416

JUL 2 8 2008

Re: k080092
Trade/Device Name: Elecsys Anti-HSHR Immunoassay
Elecsys PreciControl ThyroAB
Regulation Number: 21 CFR 866.5870
Regulation Name: Thyroid autoantibody immunological test system
Regulatory Class: Class II
Product Code: JZO, JJX
Dated: June 17, 2008
Received: June 19, 2008

Dear Ms. Greeman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding

of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan

Maria M. Chan, Ph.D.
Acting Division Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation
and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use – Elecsys Anti-TSHR Immunoassay

510(k) Number (if known): K 080092

Device Name: Elecsys Anti-TSHR Immunoassay

Indication For Use:

Immunoassay for the in vitro quantitative determination of autoantibodies to TSH receptor in human serum using a human thyroid stimulating monoclonal antibody. The anti-TSH receptor determination is used in the assessment of patients with suspect Graves' disease (autoimmune hyperthyroidism).
The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and **cobas e** immunoassay analyzers.

Prescription Use XXX (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Maria M Chan

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K080092

Indication for Use – Elecsys PreciControl ThyroAB

510(k) Number (if known): K080092

Device Name: Elecsys PreciControl ThyroAB

Indication For Use:

Elecsys PreciControl ThyroAB is used for quality control of the Elecsys Anti-TSHR immunoassay on the Elecsys and **cobas e** immunoassay analyzers.

Prescription Use XXX (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Maria M Chan

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K080092